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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,248	02/27/2007	Suk-Wah Tam-Chang	028.0002-US00	3055

92049 7590 03/31/2011

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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
03/31/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/578,248	TAM-CHANG ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,20 and 23-40* is/are pending in the application.

4a) Of the above claim(s) *1-15 and 25-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,20,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 January 2011* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11 March 2011 has been entered.

Election/Restrictions

2. Claims 1-15 and 25-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 29 June 2009.

Drawings

3. The drawings were received on 12 January 2011. These drawings are acceptable.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 16, 20, 23, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The term "substantially" in claim 16 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 20, 23, and 24, which depend from claim 16, fail to overcome this issue and are similarly rejected.

7. Claim 16 is confusing where in line 10 there occurs “sequence of any sequence.”

8. Claim 16 is indefinite with respect to what constitutes both “close proximity” and “quenching.” The term "quenching" has been construed as encompassing values of less than absolute quenching. Accordingly, the amount of change in fluorescence that constitutes "quenching", be it for a single guanosine base (claim 16) or “two or more guanosine bases” (claim 23) is less than clear.

9. Claims 20, 23, and 24, which depend from claim 16, fail to overcome these issues and are similarly rejected.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 16, 20, 23, and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

12. Attention is directed to MPEP 904.01.

> The breadth of the claims in the application should always be carefully noted; that is, the examiner should be fully aware of what the claims do not call for, as well as what they do require. During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See In re Morris, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997). See MPEP § 2111 - § 2116.01 for case law pertinent to claim analysis.

13. It is noted with particularity that narrowing limitations found in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. In re Philips Industries v. State Stove & Mfg. Co, Inc., 186 USPQ 458 (CA6 1975). While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into the claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See Ex parte Oetiker, 23 USPQ2d 1641 (BPAI, 1992).

14. Claim 16 is the only independent claim under consideration. For convenience, claim 16 is reproduced below.

16. (Currently Amended) A nucleic acid complex comprising [[an]] a capture oligonucleotide hybridized to a fluorophore-labeled oligonucleotide reporter sequence, wherein the capture oligonucleotide comprises at least one guanosine base, and a hairpin-forming sequence capable of forming a stem-loop structure, ~~and~~ wherein formation of the stem-loop ~~modifies fluorescence signals of the reporter sequence when the reporter sequence is hybridized to the first oligonucleotide~~ brings the at least one guanosine base into close proximity to the fluorophore-labeled reporter sequence when the reporter sequence is hybridized to the capture oligonucleotide, thereby quenching fluorescence signals of the fluorophore, and wherein the nucleic acid complex can detect a single-stranded nucleic acid target sequence of any sequence that can form a double-stranded hybrid with a complementary sequence in the stem region of the capture oligonucleotide, wherein the hybridization substantially disrupts the formation of the stem-loop, wherein disruption of the stem-loop produces a detectable increase in fluorescence signals of the fluorophore-labeled reporter sequence.

15. As set forth in In re Alonso 88 USPQ2d 1849 (Fed. Cir. 2008), at 1851:

> The written description requirement of 35 U.S.C. § 112, ¶ 1, is straightforward: "The specification shall contain a written description of the invention …." To satisfy this requirement, the specification must describe the invention in sufficient detail so "that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997); see also LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 [76 USPQ2d 1724] (Fed. Cir. 2005); Eiselstein v. Frank, 52 F.3d 1035, 1039 [34 USPQ2d 1467] (Fed. Cir. 1995).

Alonso at 1852:

> A genus can be described by disclosing: (1) a representative number of species in that genus; or (2) its "relevant identifying characteristics," such as "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Enzo, 323 F.3d at 964.

16. In applying the test as set forth in Alonso, it is noted that applicant is claiming a genus of nucleic acid complexes. At the very least, the complex must comprise two molecules

a. a "capture oligonucleotide" that comprises

i. at least one guanosine and

ii. a hair-pin forming sequence capable of forming a stem-loop structure; and

b. a "fluorophore-labeled oligonucleotide reporter sequence an oligonucleotide comprising a hairpin-forming sequence capable of forming a stem-loop.

17. The "nucleic acid complex" is also defined as having the capacity to "detect a single-stranded nucleic acid target sequence of any sequence that can form a double-stranded hybrid with a complementary sequence in the stem region of the capture oligonucleotide. Such language has been construed as encompassing one embodiment where the stem-loop in fact detects no target nucleotide sequence at all, as there is no target that forms a duplex structure with the "stem region of the capture oligonucleotide." And said expression has also been construed as encompassing a target-binding region of virtually any length and nucleotide composition.

18. While the claims have been amended so to recite some of the chemical/physical properties of the complex, the specification still has not been found to satisfy the written description requirements of the nucleotide sequence of the stem region, which is required to bind to target nucleic acids and affect the capture of the "capture oligonucleotide."

19. Applicant, at page 10 of the disclosure, states:

> As used herein, an oligonucleotide can be a polynucleotide and comprise at least 10, 20, 30, 40, 50, or more nucleotide residues.

Using the embodiment of an oligonucleotide of but 200 nucleotides, which is encompassed by the expression "or more", and substituting those positions with the 4 conventional nucleotides, one realizes that there are 4^{200}, or 3.2×10^{120} different oligonucleotides. In putting these numbers in perspective, it is noted that the earth is estimated to have existed for 10^{17} seconds

(see Creighton, T.E. 1983. Proteins: Structure and Molecular Principles, W. H. Freeman and Company, NY. 93-94, page 94, paragraph 1). There are an estimated 10^{79} atoms in the universe (see page 231 of Creighton, Prog. Bophys. Molec. Biol. 33:231-233, 1975). The aspect of providing all possible oligonucleotides that are 200 nucleotides in length would fill the entire universe 41 times over.

20. A review of the disclosure finds where applicant has provided a Sequence Listing as well as a further description in Table 6.

SEQ ID NO.	Length	Description (Sequence Listing)	Description (specification)
1	20	Artificial Sequence	Reporter Oligonucleotide, 5'-TAMARA labeled (p. 20)
2	20	Artificial Sequence	Reporter Oligonucleotide (p. 20)
3	79	Artificial Sequence	Capture Oligonucleotide (p. 20)
4	79	Artificial Sequence	Capture Oligonucleotide (p. 20)
5	24	Artificial Sequence	Target Sequence (p. 20)
6	67	Artificial Sequence	
7	20	Artificial Sequence	Address Oligonucleotide with Disulfide (AO/SS) (p. 20)
8	21	Artificial Sequence	Reporter Oligonucleotide, 5'-TAMARA-linked (Table 6, p. 28)
9	70	Artificial Sequence	Capture Oligonucleotide (Table 6, p. 28)
10	67	Artificial Sequence	B7-67mer (Table 6, p. 28)
11	15	Artificial Sequence	T3 (Table 6, p. 28)
12	15	Artificial Sequence	SM (Table 6, p. 28)

21. As presented above, applicant clearly contemplates oligonucleotides that are 10, 20, 30, 40, 50 or more nucleotide in length. A review of the disclosure fails to find where applicant has described any oligonucleotide, useful or not, that is 10, 30, 40, 50 or more nucleotides in length.

22. While applicant has claimed the nucleic acid complex of comprising an oligonucleotide that comprises a hairpin-forming sequence, and that this oligonucleotide is to hybridize to a fluorophore-labeled reporter sequence, applicant has not provided an adequate description of the genus of oligonucleotides that are useful, alone or in complexed formation, so that one of skill in the art would be able to identify those that are useful from those that are not useful.

23. For purposes of examination, the reporter sequence acid has been construed as encompassing not only single-stranded nucleic acids, but also double-stranded nucleic acids, be it dsDNA, dsRNA, or DNA-RNA duplexes, and that the "hybridization" that is taking place between the oligonucleotide and the reporter sequence can result in the formation of either duplex or triplex strands.

24. Applicant has not described how the various genera of such molecules are to be used in any method that has utility under 35 USC 101. Indeed, as presented above, the "artificial sequences" set forth in Table 6, as well as in the Sequence Listing, present no embodiment of useful RNA molecules, no embodiment of triplex formation, and no embodiment of a useful DNA complex, much less an adequate description of those molecules that are useful such that one of skill in the art would be able to recognize/distinguish useful from non-useful molecules.

25. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in University of California v. Eli Lilly and Co. (Fed. Cir. 1997) 43 USPQ2d at 1405, citing Lockwood v. American Airlines Inc. (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

26. Attention is directed to the decision of Fiers v. Sugano 25 USPQ2d 1604-5 (CAFC, January 1993) wherein is stated:

> We also reject Fiers argument that the existence of a workable method for preparing a DNA establishes conception of that material. Our statement in Amgen that conception may occur, inter alia, when one is able to define a chemical by its method of preparation requires that the DNA be claimed by its method of preparation. We recognize that, in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. A product-by-process claim normally is an after-the-fact definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute conception of the substance claimed as a process. Conception of a substance claimed per se without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties. . .
> * * * *
> The difficulty that would arise if we were to hold that a conception occurs when one has only an idea of a compound, defining it by its hoped-for function, is that would-be inventors would file patent applications before they had made their inventions and before they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions.

Attention is also directed to the decision of University of California v. Eli Lilly and Co. (CA FC, July 1997) 43 USPQ2d 1398 wherein is stated:

> In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing

> Amgen). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.
>
> Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

27. Accordingly, a review of the disclosure fails to find where either prong of the written description test set forth in Alonso has been satisfied. Therefore, and in the absence of convincing evidence to the contrary, claims 16, 20, 23, and 24 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Response to argument

At page 12 of the response of 12 January 2011, applicant's representative asserts:

> The specification provides ample descriptions of each of the characteristics that are listed above. For example, paragraphs [0021-0023] summarize the elements of claim 16. In addition, Figures 1-4, and 6 show detailed schematics of the oligonucleotide structure of the complex. Figures 5 and 7-11 show spectral emission data that collectively demonstrate the direct structure-function relationship between the stem-loop structure and quenching of fluorescence signals. The specification also defines guanosine base quenching as "the reduction in fluorescence emission of a fluorophore when in close proximity to guanosine bases in the sequence of a single or double-stranded nucleic acid." See Specification as-filed at ¶ [0048].
>
> All-in-all, the claims relate to a particular arrangement of nucleotide structures, as opposed to a structure that depends on a particular set of sequences. In other words, the size and sequences of the nucleic acid complex of the invention are defined by the extent that the complex is designed to: form a stem-loop structure, quench the reporter sequence fluorophore signaling by placing at least one guanosine base in close proximity to the fluorophore when the stern-loop structure is formed; and not form a stem-loop when a

> complementary nucleotide sequence hybridizes to the complementary sequence in the stem region, wherein that disruption prevents at least one guanosine base from quenching the signal of the flurophore [sic] attached to the reporter sequence. All of the foregoing features of the invention are discussed at length in the specification.

28. Agreement is reached in that the specification teaches the chemical and physical relationship between the guanosine residues and the fluorescent label; however, the specification does not provide an adequate written description of the chemical and physical properties of the nucleotide sequence(s) that bind to the target. Indicating that some undefined nucleotide binds to a target speaks to how it is to perform, and does not describe just what it is.

29. Agreement is reached in that applicant need not provide any examples or teach each and every embodiment encompassed by the claims. However, applicant is still required to enable the making and use of the full genus of compounds that are claimed and to provide a description of those embodiments in such full, clear and concise language so as to reasonably suggest that applicant, at the time of filing, had possession of the full genus of such complexes. Such full, clear and concise description has not been found. Accordingly, and in the absence of convincing evidence to the contrary, claims 16, 20, 23, and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claim Rejections - 35 USC § 102/103

30. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

31. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

32. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

33. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

34. Claims 16, 20, 23, and 24 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent Application Publication 2003/0003486 A1 (Sauer et al.).

35. Sauer et al., in the abstract and claim 1, teach of a nucleic acid complex that comprises a capture sequence that comprises a guanosine residue that quenches a fluorescent moiety when a

stem-loop is opened as a result of the capture sequence hybridizing to a target sequence, the distance between the fluorescent label and the guanosine residue(s) increases such that quenching of the fluorescent label stops and a detectable signal results.

36. In the even that Sauer et al., do not anticipate the claimed invention, such is still deemed to have been obvious in view of the well-known properties of guanosine residues and their quenching of fluorescent labels, and their incorporation into nucleic acid complexes that comprise not only stem loops but target capture sequences.

37. For the above reasons, and in the absence of convincing evidence to the contrary, claims 16, 20, 23, and 24 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent Application Publication 2003/0003486 A1 (Sauer et al.).

Conclusion

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571)272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

39. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

40. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner, Art Unit 1634